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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,676	01/04/1999	DAVID WALLACH	WALLACH=21	8997
1444	7590	04/04/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/155,676	WALLACH ET AL.
	Examiner	Art Unit
	Janet L. Epps-Ford	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on 04 April 2005.
- 2a)  This action is FINAL.                            2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 13-16,20-22,30,43-50,53-60,62-71,73-75 and 77-79 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 47,53,62,66-68,70 and 71 is/are allowed.
- 6)  Claim(s) 13-16,20-22,30,43-46,49,54,55,59,60 and 69 is/are rejected.
- 7)  Claim(s) 73-75 and 77-79 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 19 April 2000 is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 101***

1. The rejection of claims 20, 22, 50, 53-59, 63, 65, 69-71, 73-75, and 77-79 under 35 U.S.C. 101 set forth in the prior Office Action is withdrawn in response to Applicant's amendment to these claims to recite wherein the claimed polypeptides and/or nucleic acid sequences are *isolated*, and therefore do not read on a product of nature.

#### ***Claim Rejections - 35 USC § 112***

2. The rejection of claims 30, 47-49, and 64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment.

3. Claim 45 remains rejected and claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendment.

4. The rejection of claim 45 remains since the claim has not been amended as set forth in claims 47-49 and 64, to remove reference to the limitation "the cellular activity which is changed or mediated by." As stated in the prior Office Action, claim 45 recites "the cellular activity which is changed or mediated by TRAF2," there is insufficient antecedent basis for this limitation in the claim, such that the skilled artisan would be

able to ascertain which particular "cellular activity" Applicants are referring to, in order to avoid infringement. Claim 46 is also rejected for the reasons set forth above.

***Claim Rejections - 35 USC § 112-Description***

5. Claims 13-16, 20-22, 43-45, 49-50, 54-55, 59-60, 63, 69 and 77-79 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 9-05-02, and those set forth in the Official Action mailed 6-27-03.

Applicant's arguments filed 12-14-05 have been fully considered but are not persuasive. Applicants traverse the instant rejection by means of amending the claims. Specifically Applicants argue:

First, applicants hereby incorporate by reference all arguments previously made with respect to this rejection. However, in an attempt to obviate this rejection, the claims have now been amended to specify that the polypeptide "consists of" the amino acid sequence of the fragment or that the DNA sequence "consists of" a fragment of the sequence that encodes the polypeptide. Thus, the claims cannot be interpreted as reading on a completely unrelated sequence having the specified properties that has only one or two amino acids from the specified polypeptide of (a) of the claim. Indeed, it is the fragment that must have the activity, not the polypeptide that comprises the fragment.

Applicants assert that the claims have now been amended to specify that the polypeptide "consists of" the amino acid sequence of the fragment, and that the claims cannot be interpreted as reading on a completely unrelated sequence having the

specified properties of (a) of the claim. Contrary to Applicant's assertions, the current amendment to the claims does not obviate the pending rejection. Instant claim 69 part (a) recites "*comprising* the amino acid sequence of SEQ ID NO: 2, an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 6, or the amino acid sequence of SEQ ID NO: 5," and part (c) recites "*consisting of* an amino acid sequence of a fragment of (a). Therefore the scope of claim 69 encompasses an isolated polypeptide *consisting of a fragment of an isolated polypeptide comprising* the amino acid sequence of SEQ ID NO: 2, an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 6, or the amino acid sequence of SEQ ID NO: 5. To the extent that it remains that the scope of the claimed fragments may read on a completely unrelated sequence other than the amino acid sequence of SEQ ID NO: 2, an amino acid sequence encoded by the nucleotide sequence of SEQ ID NO: 6, or the amino acid sequence of SEQ ID NO: 5, due to the comprising language recited in part (a) of claim 69, the claims remain rejected for the reasons of record.

As stated in the prior Office Action, there is no clear structural correlation between the members of the claimed genus of fragments and the asserted function. The members of the claimed genus encompass polypeptides that have opposite activity, namely those that either inhibit or increase the activity of NF- $\kappa$ B. The genus of polypeptides comprising fragments having these opposing activities would be expected to be broader than a genus of polypeptides that have the same function, as indicated in Example 14 of the training materials. Therefore, contrary to Applicant's assertions, the logic used in Example 14 of the examiner training materials is not applicable in the

instant scenario. Moreover, the genus of “activities” encompassed by the instant claims is so nebulous that the “activities” of NF- $\kappa$ B could possibly encompass a broad range of undefined activities not set forth in the specification as filed, such that the skilled artisan would not be able to discern which particular activity is either increased or inhibited by the claimed polypeptide comprising said fragments.

Applicant’s arguments do not take the place of evidence that Applicant’s were in possession of the full scope of the claimed invention at the time of filing of the instant application.

***Status of Applicant Initiated Interference***

6. As stated in the prior Office Action: On 2-09-01 Applicants sought to initiate an interference between the current application and US Patents 5,843,721 and 5,844,073, wherein the proposed count was claim 3 or 4 of US 5,843,721, or claim 54 of the instant application; or all of claims 1-15 of 5,843,721 and at least claim 54 of the instant application. Additionally, in the Remarks section of the reply filed 2-09-01, Applicants stated that claims 65-68 have been added in anticipation of an interference proceeding with US Patents 5,843,721 and 5,844,073. First it is noted that the prior indication of allowability for claim 54 is withdrawn, therefore the initiation of interference proceedings will be postponed until the indication of allowability of all pending claims. If Applicants wish to file a continuation claiming only the allowable subject matter in the instant application, or cancel all non-allowable claims in the instant application, interference proceedings can then be initiated. However, until all issues are resolved in the instant

application the prosecution of this application will continue, and the interference initiation will be postponed.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 30 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothe et al. (See IDS, 12-18-98, Reference AJ).

Claim 30 recites:

30 (Currently Amended). A method for isolating and identifying a polypeptide capable of binding directly to human TRAF2, comprising applying the yeast two-hybrid procedure in which a sequence encoding said TRAF2 is carried by one hybrid vector and a sequence from a cDNA or genomic DNA library is carried by the second hybrid vector, the vectors then being used to transform yeast host cells and the positive transformed cells being isolated, followed by extraction of the extracting said second hybrid vector to obtain a sequence encoding a protein and identifying the sequence of the polypeptide encoded by said second hybrid vector, which polypeptide binds to said TRAF2.

Claim 45 recites:

45 (Currently Amended). A method for identifying and producing a ligand capable of either inhibiting or increasing the cellular activity which is changed or mediated by TRAF2 comprising:

- a) screening for a ligand capable of binding to a polypeptide comprising at least the portion of human TRAF2 having the amino acid residues 222-501 of TRAF2SEQ ID NO:23;
- b) identifying and characterizing a ligand, other than TRAF2 or portions of a receptor of the TNF/NGF receptor family, found by the screening of (a) to be capable of said binding; and
- c) producing said ligand in substantially isolated and purified form.

Rothe et al. teaches on page 1248, Figure 6, the characterization of cIAP binding to TRAF2 by means of a yeast two-hybrid system. In part (B) of Figure 6, it describes the use of construct that encodes amino acids 1 through 501 of TRAF2 in their methods.

### ***Conclusion***

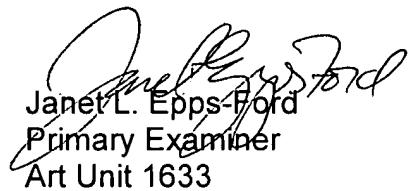
9. The instant action is not made final since the previous action did not address claims 46 and 53.
10. 13-16, 20-22, 30, 43-46, 49, 54-55, 59-60, and 69 are rejected.
11. Claims 47, 53, 62, 66-68, and 70-71 are allowable.
12. Claims 73-75, and 77-79 are objected to as being dependent on a rejected base claim.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Janet L. Epps-Ford  
Primary Examiner  
Art Unit 1633

JLE